Government's Appeal in Supreme Court on Drugs Price Fixation Cases

144. SHRI BHUBANESWAR KALITA : Will the Miinster of INDUSTRY be pleased to state:

(a) whether it is a fact that his Ministry filed an appeal in the Supreme Court against the judgment of Delhi High Court in regard to price fixation cases of drugs and finished medicines;

(b) whether it is also a fact that the Supreme Court allowed the appeal;

(c) whether it is also a fact that the Supreme Court gave certain directions to his Ministry; and

(d) if so, what are the details of the directions and what action has been taken on the directions?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH): (a) to (c) Yes, Sir.

(d) The Supreme Court has directed the Government to give hearings to petitioner companies within 2 months of date of judgment and dispose of the representations within 15 days of conclusion of the hearing. Hearings have already been given to all the affected companies.

Ex-factory Value of Production of Bulk Drugs

145. SHRI BHUBANESWAR KALITA : Will the Miinster of INDUSTRY be pleased to state :

(a) whether it is a fact that drug compaines have been inflating the ex-factory value of production of bulk drugs in their ratio parameters figures ;

(b) if so, what is the definition of ex-factory value of production of bulk drugs ;

(c) whether it is also a fact that drug companies have been taking national and maximum selling prices as ex-factory value ;

(d) if so, whether his Ministry has issued any guidelines in this regard ;

(e) if so, what are the dedtails thereof ;

(f) whether his Ministry has adopted any method for verification of ex-factory value of production of bulk drugs; and

(g) if so, what are the details thereof?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH) : (a) No such report has been received.

(b) At present ex-factory value of production includes all costs incurred on product, including overheads, till the product leaves the factory.

(c) No such report has been received.

(d) No such guidelines have been issued.

(e) Does not arise.

(f) and (g) Chartered Accountant's Certificate regarding ex-factory value of production is the basis for verification.

Ratio Parameters for Drug Industry

146. SHRI BHUBANESWAR KALITA : Will the Minister of INDUSTRY be pleased to state :

(a) whether it is a fact that his Ministry proposed for revision of ratio parameters for the Drug Industry ;

(b) if so, what were earlier parameters in the Drug Policy, 1978 and what is the revised proposal ;

(c) whether his Ministry issued any guidelines regarding ratio parametres ;

(d) if so, the details thereof ;

(e) whether it is a fact that a number of companies are marketing formulations under their own brand names based on imported bulk drugs after gettig them manufactured from SSI units ;

(f) if so, whether such imports will be taken in ratio parameters ; and

(g) if not, what are the reasons therefor?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH) : (a) and (b) Details are given in the Statement annexed [See Appendix CXLIII, Annexure No. 24].

(c) and (d) Pharmaceutical Industry Associations have been requested to advise the drug manufacturing companies in the organised sector to organise their production programme so that they achieve the revised ratio-parameters between the ex-factory value of production of bulk drugs and formulations within a period of 3 years as stipulated in the new measures announced by the Government in December, 1986.

(e) Some such instances have come to the notice of the Government.

(f) No, Sir.

(g) For the purpose of ratio parameters, only those bulk drugs are taken into account which are actually imported by such companies.

Phased Manufacturing of Bulk Drugs

147. SHRI BHUBANESWAR KALITA : Will the Minister of INDUSTRY be pleased to state :

(a) whether his Ministry has proposed a phased manufacturing programme for the production of bulk drugs ;

(b) whether it is a fact that no penalty provision has been proposed if phased manufacturing programme is not implemented by the Drug Companies ;

(c) if so, how the objective will be achieved without such a provision ;

(d) whether it is also a fact that his Ministry recommended certain approvals on phased manufactured programme ; and

(e) if so, the names of the drug companies along with the names of bulk drugs, stage of manufacture, name of penultimate or intermediate and the details of the programme in each case?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETRO CHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R. K. JAICHANDRA SINGH) : (a) Yes, Sir.

(b) and (c) The phased manufacturing programme will be a condition of the industrial approval and non-compliance may result in cancellation of the approval.

(d) and (e) Only two approvals on Phased Manufacturing programme have so far been granted which were from basic stage righ tfrom the beginning and as such no phased indigenisation was involved. Details of these approvals are as under :—

Name of the company	Name of the bulk drug	Stage of Manufacture/ Programme	Raw material to be used
1. M/s. Unique Chemicals.	(a) Methyl Imidazole	Basic right from the beginning	Glyoxal
	(b) 2-Methyl 5-Nitro Imidazole	Do.	Acetaldehyde
	(c) Metronidazole	Do.	Ammonia
2. M/s. Ranbaxy Labs. Ltd.	(a) Doxycycline	Do.	Oxytetracycline.